4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Carbarsone; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs) for roxarsone or carbarsone Type A medicated articles at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007, has requested that FDA withdraw approval of the following three NADAs because the products, used to manufacture Type B and Type C medicated feeds, are no longer manufactured or marketed: NADA 007-891 for 3-NITRO (roxarsone) Type A medicated article, NADA 092-953 for Roxarsone Type A Medicated Articles, and NADA 010-285 for CARB-O-SEP (carbarsone) Type A medicated article.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of

withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 007-891, 092-953, and 010-285, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: November 18, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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